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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,691	07/20/2001	Ping Gao	28341/00222.US1	9971
47376	7590	06/29/2005	EXAMINER	
HARNES, DICKEY & PIERCE, P.L.C. 7700 BONHOMME SUITE 400 ST LOUIS, MO 63105			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/909,691

Applicant(s)

GAO ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 6-20 and 25-40 is/are pending in the application.
- 4a) Of the above claim(s) 28-36, 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-20, 25-27 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt of amendment and remarks dated 4-15-05 is acknowledged.

New claims 36-40 have been added. Claims 1-3, 6-20 and 25-40 are pending. Claims 1-3, 6-20 and 25-27 directed to the elected invention have been examined. Newly added claim 37 is dependent upon on claim 1. Accordingly, claims 1-3, 6-20, 25-27 and 37 are considered for examination. Claims 28-36 and 38-40 have not been withdrawn from considered as directed to non-elected invention.

The following rejection of record has been maintained:

#### ***Claim Rejections - 35 USC § 103***

Claims 1-3, 6-20 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/03113 (WO) in view of US 6,660,286 to Lambert et al (Lambert).

Instant claims are directed to a self-emulsifying drug delivery (SEDD) system comprising an extremely water-insoluble lipophilic active agent, a fatty aid, a surfactant and polyvinylpyrrolidone (PVP), wherein the molecular weight of PVP is about 2,500 to about 20,000 and the weight ratio of fatty acid to PVP is 2:1 to 1:3. Dependent claims further limit the ratio of surfactant to PVP; recite specific surfactants, fatty acids, active agents etc.

WO '113 teaches a SEDD system for increasing bioavailability of water insoluble or oil soluble drugs, comprising the 0.1% t 17% drug, 2% to 50% of a solubilizer, 10% to 55% of an emulsifier and oil (claim 1 and pages 6-7, page 8, lines 14-24). Particularly, WO '113 teaches the claimed emulsifiers (page 7) and their solubilizers include fatty

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acids such as oleic acid, linoleic acid (lines bridging pages 7-8). The percentages of drug, solubilizer and surfactant taught by WO are within the claimed range. Further, WO also teaches the claimed surfactants such as polyoxyethylene glycerides (page 7). WO' 113 teaches oral administration of the composition in the form of gelatin capsules (page 8, lines 25-28). WO does not teach PVP of the instant claims and also fails to teach specific drugs of claim 20. However, WO suggests that the composition can be used with any active agents such as protease inhibitors or other active agents (page 10). WO further teaches addition of antioxidants such as BHA, ascorbic acid etc.

Lambert teaches emulsion vehicles for poorly soluble drugs such as paclitaxel comprising a solvent, tocopherol polyethylene glycol succinate or PEGylated TGPS, a poorly water-soluble drug, a co-solvent such as NMP or polyvinylpyrrolidone and a surfactant (col. 5). In a preferred embodiment, Lambert suggests that the co-solvent may be polyvinylpyrrolidone, or PEG or NMP (col. 5, lines 34-37). In particular, Lambert teaches PVP having a molecular weight between 2,500 and 100,000 and at a concentration of 1% to 5%, which is within claimed range (col. 3 and col. 7). Lambert suggests that using solvents and co-solvents, mentioned above, avoids the necessity of solubilizing poorly soluble active agents in monohydric alcohols and other volatile solvents, and further eliminates the need for removal of solvents prior to emulsification. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add co-solvent, PVP having a molecular weight between 2500 and 100000, in the self-emulsifying drug delivery system of WO. Further, choosing the appropriate molecular weight of PVP and the ratio of insoluble active agent to co-

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solvent (PVP), as well as the ratio of different co-solvents such as fatty acids (WO) and PVP (Lambert), with an expectation to successfully solubilize the poorly water-soluble active agents without the need to employ volatile solvents.

**New claim 37 has been rejected under this section for the reasons mentioned in the above paragraph. Further, instant claim recites “for parenteral”, which is an intended use. Besides, Lambert teaches parenteral administration and hence administering the composition by parenteral route would have been within the scope of skilled artisan.**

### ***Response to Arguments***

Applicant's arguments filed 4-15-05 have been fully considered but they are not persuasive.

Applicants argue that while there is no motivation to combine Lambert and WO '113, the teachings of Lambert and WO '113 are contradictory to each other and thus teach away from such a combination because Lambert repeatedly states that their composition is free of ethanol and WO '11 prefers the presence of ethanol. Applicants argue that the contradictory teachings cannot be combined to support a prima facie showing of obviousness and hence the rejection should be withdrawn.

Applicants' arguments are not found persuasive because instant claims do not recite the argued limitation and besides, omission of an element and its function is obvious if the function of the element is not desired. In addition to ethanol, WO '113 also

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teaches other solubilizers. The prior art teachings are not limited to preferred embodiments and instead should be considered as a whole. WO '113 also teaches composition with other solubilizers such as propylene glycol and accordingly it would have been obvious for one of an ordinary skill in the art to prepare compositions with and without ethanol, and the combination of references still results in the claimed SEDD.

Applicants argue that at least some of the claims also are patentable over a combination of Lambert and WO '113 because instant claims 6 and 18 specifically recite the concentration of 5% to 40%, which not taught by either of the references, in the context of self-emulsifying drug delivery systems. Applicants argue that Lambert teaches away from the concentrations claimed because the reference teaches only up to 5%. Applicants' arguments are not persuasive because as applicants themselves admit Lambert teaches %5 of PVP, which overlaps with the claimed range of PVP percentages and thus does not teach away from the claimed percentages. It is well established that in the case where the claimed ranges overlap or lie inside the ranges disclosed by the prior art, a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191USPQ 90 (CCPA 1976). Therefore, the rejection has been maintained.

Applicants request rejoinder of the claims 28-36 and 38-40, currently restricted, because process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. However, even though the non-elected claims are

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amended to recite the limitations of elected claims, applicants' arguments are not persuasive because the non-elected claims are directed to a different invention that is distinct from the elected claims (directed to a composition). Therefore, the non-elected claims are not rejoined.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

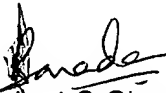
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
June 23, 2005

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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